Maryland: Clinical Advisory Group on Cardiac Surgery and PCI
DISCUSSION DOCUMENT: Summary of current guidelines, CPORT-E criteria, and current Maryland standards

KEY Source Documents:

2011 PCI GL = 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention. ACCF, AHA Task Force on Practice Guidelines, SCAI, Glenn N. Levine, et al. Journal of the American College of Cardiology, published online Nov. 7, 2011.

2012 ECD = 2012 ACCF/SCAI Expert Consensus Document on Cardiac Catheterization Laboratory Standards Update. ACCF Task Force on Expert Consensus Documents, STS, SVM, Thomas M. Bashore, et al. Journal of the American College of Cardiology, published online May 8, 2012.

AHA Policy Guidance = American Heart Association. Percutaneous Coronary Intervention (PCI) without Surgical Back-up: Policy Guidance. March 7, 2012.

British GL = KD Dawkins, et al, Joint Working Group on Percutaneous Coronary Intervention of the British Cardiovascular Intervention Society and the British Cardiac Society. Percutaneous Coronary Intervention: Recommendations for Good Practice and Training. Heart 2005; 91(Suppl VI): vi1-vi27.

2008 Performance Measures = ACC/AHA 2008 Performance Measures for Adults with ST-Elevation and Non-ST-Elevation Myocardial Infarction. HM Krumholz, et al. Circulation 2008, 118:2596-2648.

"Current" = Currently in Maryland State Health Plan. In general, the basis for current regulations came from protocols of the CPORT studies.

Guideline Area: Who (hospital / practitioner) provides PCI?	Guideline	For program establishment and/or ongoing performance?
Institutional development and ongoing performance 1. Provide primary PCI as routine, treatment of choice for all appropriate AMI patients 24 hours per day, seven days per 2. Have adequate physician, nursing and technical staff to provide cardiac cath lab and coronary care unit services to acute MI patients 24/7. 3. Provide written commitment by hospital administration signed by the hospital president to support the program. 4. Complete a PCI program development plan, to involve additional training in multiple care areas, e.g., emergency room, catheterization lab, coronary care unit and step-down unit. The plan shall include logistical plans including plans for recurrent ischemia or infarction, plans for failed angioplasty, and fall-back plans for primary angioplasty system failure, and a quality and error management system. Detailed description of recommended plan components is in C-PORT E Manual of Operations. 5. Perform risk stratification for all CCL intervention patients. 6. Maintain at least 1.5 FTE for data management and reporting, including an RN medical data coordinator.	1 – 6: Current; 2012 AHA Policy Guidance; 2012 ECD.	Both
Additional requirements for programs without onsite cardiac surgery 1. Provide a formal written agreement with a tertiary institution that provides for unconditional transfer of patients for any required additional care, including emergent or elective cardiac surgery. 2. Provide a formal, written agreement with an advanced cardiac life support emergency medical services provider that guarantees arrival of air or ground ambulance within 30 minutes of call. 2a. Alternative to #2 -- have agreement guaranteeing arrival of EMS within 20 minutes of call. 3. Adhere to Device Selection agreement, related to prohibition of atherectomy. "[PCI at non-surgical hospitals] should only be made available where there are written and enforceable guidelines from a full-service facility willing to accept patients should complications arise. Partnership with an experienced tertiary care hospital with a PCI program supported by cardiovascular surgery is mandatory." (2012 ECD)	1. Current 2. Current 2a. 2012 ECD 3. Current	Both

Institutional case volume		
Note: Institutional volume is calculated using a rolling 8-quarter interval. (2012 ECD)		
1. The target volume for facilities performing both primary and elective procedures is 200 PCI/year, to include a minimum of 36 primary PCI/year.	1-2: 2011 PCI GL, 2012 ECD	Ongoing
2. Programs with <200 PCI/year (in two consecutive years) will be reviewed on an individual basis, specifically whether their performance metrics are equivalent to accepted benchmarks, and whetherthey are in geographically isolated or under-served areas.		Ongoing
3. Program volume of 150 PCI / year is considered an absolute minimum threshold, below which a program cannot operate, for longer than two consecutive years.	3. 2007 SCAI Expert Consensus Document	Both
4. New programs will have 2 years to reach the absolute minimum volume, but after that programs failing to reach this volume for 2 consecutive years will not remain open under any circumstances.	4-5: 2011 PCI GL, 2012 ECD	Establishment
5. Track risk-adjusted outcomes (can be through NCDR registries).		Both
Institutional performance		
1. Maintain primary PCI door-to-balloon time <=90 minutes in >=75% of appropriate cases. o Denominator will consist of 100% of cases with AMI patients presenting with ST-segment elevation or LBBB on ECG who received primary PCI. Includes cases which are dropped for NCDR aggregate measures. o Regularly review cases that were excluded from NCDR benchmarking (>90 minutes DTB time, for non-system or other reasons, e.g. difficulty crossing lesion).	1. AHA Mission Lifeline Goal	Both
1a. An alternate measure : median time from hospital arrival to primary PCI is < =90 minutes among AMI patients with ST-segment elevation or LBBB on ECG who received primary PCI.	1a. 2008 Performance Measures	Both
Operator performance / training		
Note: Operator volume is calculated using a rolling 8-quarter interval. (2012 ECD)		
1. All interventionalists performing PCI shall have certification from the American Board of Internal Medicine in interventional cardiology and participate in the maintenance of certification program.	1. 2011 PCI GL	Both
2. Primary PCI operators should perform at least 11 primary PCI per year. This is a **target**, and will be reviewed along with other measures; and it may be changed, pending revised Clinical Competency statement.	2. 2011 PCI GL	Both
3. The **target** volume for total PCI per operator is 75/year**,** and will be reviewed along with other measures; the target may be changed, pending revised Clinical Competency statement.	3. 2011 PCI GL; British GL	Both
4. All primary PCI procedures must be reviewed by a designated QA committee, regardless of operator volume.	4. 2012 ECD	Both
5. Operators must complete a minimum 12 hours of CME per year.	5. 2012 ECD	Both
6. The CCL Medical Director will review the clinical performance of operators with <target volume, averaged over two years.	6. [*de novo]*	Both
CCL (PCI Program) Director		
7. CCL Medical Career, beyond above, must have a lifetime performance of at least 500 PCI cases.	7. 2012 ECD	Both
Quality Assurance/ Quality Improvement		
Each PCI program shall operate a quality-improvement program that routinely: 1. Reviews quality and outcomes of the entire program; 2. Reviews results of individual operators; 3. Provides peer review of difficult or complicated cases; 4. Performs random case review. 5. Performs blinded review. 6. Includes risk adjustment (can be achieved through NCDR registry participation)	1-4,6: 2011 PCI GL	Both

	Guideline	For program establishment and/or ongoing performance?
7. CQI Recommended Components · Standing committee with chairman and staff coordinator · Database and data collection · Data analysis, interpretation, and feedback · Goals outlined to eliminate outliers, reduce variation, and enhance performance · Incorporation of practice standardization/guidelines · Thresholds for intervention · Appropriate use assessment *[tool to be determined by the program]* **Individual-level quality of care review** · Risk-adjusted outcomes, if statistical tools available. · Individual data benchmarked against the ACC-NCDR or similar database · Appropriateness of procedures **Laboratory-level quality of care review** · Risk-adjusted outcomes (can be achieved through NCDR registry participation. · Comparison with similar institutions · Lab data benchmarked against national databases (e.g., ACC-NCDR) · QA staffing to monitor appropriate use, complications, and outcomes · Weekly lab conferences. · Regular mortality and morbidity conferences and a review of all major complications.	All: 2012 ECD	Both
Guideline area: Which Patients?		
Primary PCI Patient Exclusions for non-SOS programs (subject to updating by ACCF/AHA/SCAI) 1. patients with EF<30% 2. unprotected Left Main intervention 3. intervention on last conduit to the heart 4.pediatric cases **For considerations of patient suitability for primary PCI, including "high-risk" patient characteristics, the program practice will be guided by the ACC/AHA/SCAI national guidelines and consensus document;** the program shall update the definition of high-risk patient characteristics as guidelines and consensus documents are revised. **Elective PCI patient exclusions** (CPORT-E criteria) 1. High likelihood of requiring a device not available at non-SOS site (i.e., atherectomy device, cutting balloon except within stents for in-stent resenosis). 2. PCI of unprotected left main coronary artery (high procedural risk) 3. PCI of left circulation lesion in the presence of critical (>70%) unprotected left main coronary artery lesion (high 4. Poor LV function -EF<=20% and need to perform PCI in a vessel supplying significant myocardium.	1-3: AHA Policy Guidance CPORT-E patient criteria 2012 ACCF / SCAI ECD "patients who may be unsuitable for PCI in non-SOS facility" CPORT-E criteria	Both Both
For considerations of patient suitability for non-primary PCI, including "high-risk" patient and lesion characteristics, the practice will be guided by current ACC/AHA/SCAI national guidelines and consensus documents; the program shall update the definition of	2012 ACCF / SCAI ECD	Both

Guideline area: How is PCI performed?		
Heart Team Approach		
1. **Heart Team approach for surgical and non-surgical sites –** For patients with unprotected left main or complex CAD. This team consists of an interventional cardiologist and a cardiac surgeon to: a. review patient's medical condition and coronary anatomy; b. determine that PCI and/or CABG are technically feasible and reasonable; and c. discuss revascularization options with patient before a treatment strategy is selected. Note: Calculation of STS and SYNTAX are encouraged as part of evaluation.	1. 2011 PCI GL	Both
2. **At sites without cardiac surgery:** To facilitate the above, there shall be a written collaborative agreement, signed by both institutions, and by [cardiac] surgical director at tertiary hospital, and CCL medical director at non-SOS hospital, that includes patient criteria for Heart Team participation in decision-making, and specified frequency of face-to-face meetings between physicians at both hospitals. An ongoing working relationship between the interventional cardiologists and cardiothoracic surgeons at the tertiary hospital must be established.	2. 2012 ACCF / SCAI ECD	Both
Adjuvant diagnostic tests		
3. MHCC will review NCDR or other available data on the use of FFR at the hospital level. Basis: It is reasonable for a program to use fractional-flow reserve to assess angiographic intermediate coronary lesions (50% to 70% diameter stenosis) and for guiding revascularization decisions in patients with SIHD.	3. 2011 PCI GL	Both
4. MHCC will review NCDR or other available data on the use of IVUS at the hospital level. Basis: It is reasonable for a program to use IVUS for assessment of angiographically indeterminant left main CAD.	4. 2011 PCI GL	Both
General procedural considerations		
5. In general procedural considerations (e.g., choice of strategy for Unstable Angina/ NSTEMI, strategy for specific comorbidities, including renal insufficiency, diabetes, etc) should include most recent ACCF/AHA/SCAI guidelines.	5. [*De novo]*	Both